Home-based rehabilitation after TIA or minor stroke: pilot randomised trial of 'The Healthy Brain Rehabilitation Manual'

Authors: Neil Heron PhD,[1,2,3] Frank Kee MD,[2,3] Jonathan Mant MD,[4] Margaret E Cupples MD,[1,2,3] Michael Donnelly PhD[2,3]

Affiliations:
[1]Dept of General Practice and Primary Care, Queen's University, Belfast
[2] Centre for Public Health Research, Queen's University, Belfast
[3]UKCRC Centre of Excellence for Public Health Research (NI)
[4]Primary Care Unit, Department of Public Health and Primary Care, University of Cambridge, Strangeways Research Laboratory, Cambridge, UK

Corresponding author: Dr Neil Heron

Address: Dept of General Practice, Queen's University, 1 Dunluce Avenue, Belfast, BT9 7HR.

Telephone: 0044(0)7808774292

Email: nheron02@qub.ac.uk

Twitter: @neilSportDoc

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Abstract

Background

Whilst the importance of secondary prevention after transient ischaemic attack (TIA) or minor stroke is recognised research is sparse regarding novel effective ways in which to intervene in a primary care context.

Aim

To pilot a randomised controlled trial of a novel home-based prevention programme ('*The Healthy Brain Rehabilitation Manual*') for patients with TIA or 'minor' stroke.

Design and setting

Pilot randomised controlled trial, home-based.

Method

Patients within 4 weeks of a first TIA or 'minor' stroke received study information from clinicians in 4 hospitals. Participants were randomly allocated to: (1) standard care (control group) (n=12); (2) standard care, manual and GP follow-up (n=14); (3) standard care, manual and stroke nurse follow-up (n=14). All groups received telephone follow-up at 1, 4 and 9 weeks. We assessed eligibility, recruitment and retention; measured stroke/cardiovascular risk factors at baseline and 12 weeks; and elicited participants' views about the study via focus groups.

Results

Over a 32-week period, 28% of clinic attendees (125/443) were eligible; 35% (44/125) consented to research contact; 91% (40/44) participated: 98% (39/40) completed the study.

After 12 weeks, stroke risk factors improved in both intervention groups. The research methods and programme were acceptable to patients and health professionals who commented that the programme ‘filled a gap’ in current post-TIA management.

Conclusions

Our findings indicate that implementation of this novel home-based CR programme, and of a trial to evaluate its effectiveness, is feasible, with potential for clinically important benefits and improved secondary prevention following TIA or ‘minor’ stroke.

Keywords: cardiac rehabilitation; stroke; transient ischaemic attack; home-based program; randomized controlled trial; pilot study; secondary prevention

Introduction

The immediate period after a transient ischaemic attack (TIA) or 'minor' stroke is a crucial time to intervene to reduce risk of future cardiovascular events (1)(2), with General Practitioners (GPs) often managing this secondary prevention. Organisational interventions in general practice for secondary prevention of cardiovascular disease reduce mortality (3) and participation in cardiac rehabilitation (CR) programmes following acute cardiac events are associated with reduced mortality and morbidity (4)(5). Home-based CR programmes may be as effective as those delivered in hospitals, with better compliance (4). However, whilst cardio- and cerebro-vascular disease share common pathological mechanisms and risk factors, the impact of CR and lifestyle interventions post-stroke and TIA requires further research (6)(7)(8). Furthermore, physical activity, a core element of CR, is supported by different behaviour change methods including goal setting, providing feedback, and monitoring, and by using pedometers (9)(10) but there are few studies of pedometer use by patients early after TIA or stroke (11)(12).

After systematically reviewing the underpinning evidence (7)(16), *'The Healthy Brain Rehabilitation Manual*', an adaptation of the 'Heart Manual' (13), was developed by following Medical Research Council (MRC) guidelines (14) and the results of a feasibility study, with service user input (7)(15)(16).

Aim

We conducted a pilot trial of the effectiveness of a revised version of '*The Healthy Brain Rehabilitation Manual*' during the acute period following a first TIA or 'minor' stroke. We assessed rates of recruitment, retention and completion of outcome measures, explored participants' views about the intervention and research methods, and obtained an estimate of the intervention's potential effect on cardiovascular risk factors.

Methods

The Office for Research Ethics Committees, Northern Ireland (NI) approved the study (REC reference 15/NI/0001, 21/09/2015). Our report follows CONSORT guidelines (17) and the PREPARE trial guide (18).

Study Setting and participants

Nurses working in 'drop-in' TIA clinics and scheduled outpatient clinics in four TIA/'minor' stroke assessment units in different NI Health and Social Care Trusts identified eligible patients and gave them study information. Patients who consented to contact were telephoned by the researcher the following day and invited to participate.

Eligibility Criteria

Patients were included if they were aged 18 years or older, within 4 weeks of their first TIA or 'mild' stroke symptoms, with diagnoses attributed to atherosclerosis or small vessel occlusion (19)(20). Patients with unstable cardiac conditions, contraindications for exercise training (21) or a previous cerebrovascular event were excluded. A stroke research nurse (SN) recorded patients with a TIA and/or 'minor' stroke diagnosis who were eligible to participate, agreed to be contacted and consented to participate.

Data collection

At baseline and after 12 weeks participants attended the NI Clinical Research Facility (NICRF), Belfast City Hospital for assessment: a minor protocol amendment, after five

months' recruitment, allowed the option of home assessments. We measured height and weight (light clothing; Seca scale, model 799), waist circumference, resting blood pressure and heart rate (using BpTRU, model BPM-200 (22)), checked the heart rhythm for dysrhythmias (radial pulse; 1 minute) and recorded socio-demographic variables, smoking status, alcohol intake (units in typical week before assessment), time from event, educational status and current employment. We derived a measure of deprivation (multiple deprivation measure (MDM)) from home address postcodes (23), enquired about family history, assessed physical activity (validated International Physical Activity Questionnaire (IPAQ))(24)) and calculated a Mediterranean Diet Score using a validated questionnaire (25). A 2-minute walk test was performed twice, separated by a rest period of at least 30 minutes (26). We assessed anxiety and depression (Hospital Anxiety and Depression (HADs) questionnaire) (27), disability (Modified Rankin scale) (28), 'readiness to change' (29), quality of life (EQ5D-5L, http://www.euroqol.org/eq-5d-products/eq-5d-5l.html) (30) and administered a Timed Up and Go test (31). Participants were invited to wear a wrist-worn, tri-axial accelerometer, Axivity AX3, for one week on their dominant wrist for objective measurement of physical activity (32) and to return this in a pre-paid envelope.

The Intervention

'*The Healthy Brain Rehabilitation Manual*' has been described previously (15). Briefly, it included information about TIA and stroke, advice about healthy lifestyle and a stroke risk reduction plan that focused on a different risk factor each week for six successive weeks; it promoted physical activity by setting and reviewing weekly pedometer step-count targets. Telephone follow-up calls at 1, 4 and 9 weeks by a General Practitioner (GP) (Group 2) or SN (Group 3) supported its use.

Randomisation and blinding

An independent statistician generated random permuted blocks of 3 and placed the allocations in sealed, opaque envelopes, opened only after completion of baseline assessments. A research nurse, blinded to intervention allocation, undertook post-intervention assessments.

Study design

The RCT comprised three study arms: Group 1 (control) received standard post-TIA/minor stroke care (13)(33). In addition, at the end of their baseline assessment, Groups 2 and 3 received '*The Healthy Brain Rehabilitation Manual*' and a wrist-worn pedometer (Yamax Digi-Walker CW-701), with a daily step-count and physical activity diary. Groups 2 and 3 were informed about UK physical activity guidelines and how to achieve moderate and vigorous physical activity (MVPA) intensity (34), reduce sedentary time, and set and monitor physical activity goals using the pedometer.

All participants were telephoned at 1, 4 and 9 weeks, to address any concerns regarding their care. Groups 2 and 3 were also asked to report weekly average step-counts and encouraged to self-set step count targets (9), using the '5 As' approach (35), motivational interviewing techniques (36) and a standardised format. Groups 1 and 2 received GP telephone follow-up; Group 3 received SN telephone follow-up. Diary records were reviewed at 12-week follow-up.

Data analysis

We estimated that data on 40 participants were required to inform planning of a randomised controlled trial. An independent statistician, blinded to group allocation, used SPSS, version

23 to report descriptive statistics. We compared accelerometer data with diary records, using a minimum of 72 hours wear time to define valid data (32), removing non-wear time (consecutive stationary periods lasting 60 minutes or longer (32)) prior to analysis using the Esliger formula (https://axivity.com). We categorised output data as sedentary time and light, moderate and vigorous physical activity, adding the latter categories to calculate mean Group MVPA.

Qualitative study

Participants, selected purposively by gender, age, clinical condition and Group allocation, were invited to a focus group discussion. Both SNs who delivered Group 3 follow-up were interviewed jointly. The focus group and interview were audio-recorded with consent, lasted approximately one hour and 20 minutes, respectively, and were transcribed verbatim. Primary questions related to research procedures, methods and the intervention's acceptability (**Supplement, File** 1). Two researchers (NH, MD) coded the transcript content independently, using a deductive approach to content analysis; a third researcher helped resolve any differences in coding and agree the categories and themes identified before discussion with the research team.

Results

Recruitment, retention and completion of assessment measures

During 32 weeks recruitment (08/05/2017 to 22/12/17), 28% (125/443) of clinic attendees, diagnosed with TIA and/or 'minor stroke' (**Figure 1**), were eligible for inclusion; 35.2% (44/125) agreed to research contact; 91% of these (40/44) consented to participate; 60% (24/40) were male and all were white British and/or Irish citizens. Previous cerebrovascular events or non-atherosclerotic diagnoses were the main reasons for ineligibility.

One participant (Group 3) dropped out before beginning the intervention due to work commitments; 97.5% (39/40) participants completed the study and 12-week follow-up. Two participants completed baseline home assessments; both attended the NICRF for 12-week follow-up.

Baseline characteristics

Participants included 24 males (24/40; 60%); 26 (65%) had a TIA and 14 a minor stroke diagnosis. Mean time from event onset to enrolment ranged from 15 days (Group 2) to 19 days (Group 1). They were aged 38-88 years old; 67.5% (27/40) attained only High school level education; 57.5% (23/40) lived in the 50% most disadvantaged areas of NI. Nine were ex-smokers; 11 currently smoked; mean alcohol intake was <14 units/week.

Baseline distributions were similar across all groups for mean systolic and diastolic blood pressure (SBP and DBP), waist circumference and body mass index (BMI) **(Table 1)**. For all Groups, mean SDP and DBP was ≤140/90mmHg; mean waist circumference and BMI reflected that most participants were overweight. Mediterranean diet scores were poor and mean total HADs scores were elevated, particularly for anxiety.

Baseline IPAQ scores indicated that 21 participants were physically inactive; 72.5% (29/40) reported sitting for 5 or more hours daily. Accelerometer data were returned by all participants; one dataset was excluded from analysis (<72 hours' wear time). All Groups showed similar sedentary time (approximately 20.5 hours/day).

Post-intervention results

Groups 2 and 3 showed greater improvements than Group 1 in mean BMI and waist circumference; in Mediterranean diet, IPAQ (MET minutes/week and sitting time), HADs and EQ5D-5L scores; and in 2MWT and TUGT performance **(Table 1)**. Mean daily step

counts increased in Groups 2 and 3. Three participants, all aged >80 years and frail, thought the pedometer under-counted their steps; 5 lost their pedometer; one discontinued using it due to skin irritation. At follow-up, 2 accelerometers were lost in the post; 37 returned valid data.

One participant, wheelchair-bound, could not use a pedometer: their 2MWT, TUGT, and BMI were not measured. One stroke event occurred during follow-up, in the control group. No adverse events were reported.

Qualitative Results

Four participants (1 male, 3 female; 3 Group 3; 1 Group 2; age range 50-80 years) attended the focus group. The SNs (female) were interviewed together. Three main themes were uncovered as reported below with examples of anonymised supporting quotes.

1. Use of the manual

Participants and SNs approved the manual, commending its physical dimensions and format.

> *"So the size was nice, it was nice to handle and it was very clearly written. There was good feedback from patients about the manual." (N1)*

In particular, pictorial information was noted in terms of encouraging behaviour change.

> *"the easiest thing for me was, with regards eating, the picture of the plate with the proportions you should have on it. So, for example, half your plate should be vegetables." (60yo, male)*

Some participants read it once; others re-read it after follow-up contacts.

> *"I just read it as a one off and … that was good enough for me … got an idea about diet and exercise, so the message was there." (60yo, male).*

"When the nurses rang, I was like, oh I better get the manual out again and read over those sections again…" (83yo, female)

Family members viewed it as a useful source for healthy living advice.

"It works well when you read it and then discuss it with someone. She [the stroke nurse] could point out things …… to pick up on…" (57yo, female)

"Yes my daughter too [read the manual]….. she tried to help me with easy to make healthy food." (60yo, male)

2. Study design

Participants identified no problems with the recruitment process and noted positively that participation provided the benefit of follow-up, which was unavailable within routine NHS care.

"I thought that was a good thing….. to have some aftercare." (60yo, male).

"I was really glad that there was something there as a back-up because I wasn't sure about the medication…. ." (78yo, female)

"I got quite a shock after my stroke …., I was glad to have someone follow me up and to know if there is something I can do to avoid having another one…" (83yo, female

The SNs suggested that it would have been appropriate to include patients with cardio-embolic and previous cerebrovascular events, as these were *"two things which restricted our recruitment".* Few patients were dissuaded by the logistics or challenges of travelling to the assessment centre (travel expenses were covered).

"....it maybe put off some of the more elderly participants, who didn't have any transport." (N1)

".... the last time, it was bucketing [raining].... by the time I got home, I was drenched. So today I thought, I'll take a taxi....." (83yo, female)

Conducting assessments in local hospitals was not considered a better option. Baseline assessment and individually tailored goals were regarded as key intervention components.

"I think the actual meeting is more powerful than reading the manual. The other thing was, you know you're coming back, so you have that accountability." (60yo, male)

Participants recognised the standardised format of follow-up calls and perceived no differences between SN or GP delivery; follow-up facilitated compliance with the programme and, on average, lasted 5 minutes.

"I don't think it makes a difference if you're followed up by a GP or SN because it's all about the conversation and the questions you were asked." (57yo, female)

" it was motivating.... someone was showing an interest in you." (60yo, male)

Three telephone calls provided sufficient support and no other format of follow-up was suggested by participants. SNs felt confident about delivering follow-up but commented that access to a patient's electronic healthcare record would provide reassurance.

"The thing which I found difficult was that we were phoning people 'cold' if you like, there was no background." (N2)

Pedometers were valued for self-monitoring physical activity, though one participant considered that their measurement was unreliable. SNs lacked confidence to address problems regarding pedometers but suggested this could be overcome with appropriate training.

"I'm not too good with technology plus I hadn't actually seen the pedometer." (N2)

No issues regarding any assessment measurements were identified.

".....they were fine to do." (57yo, female).

3. Suggested changes

All participants and SNs were positive about the intervention and the study:

"It was a very positive thing to be involved with, with lots of positive feedback from the patients."

One suggestion was to provide an option of using an electronic or paper version.

"... you would have to give people both options but yes, it's [an electronic version] a good idea." (N2)

Participants described persistent symptoms following their event, including increased anxiety and fatigue, shock following diagnosis, and worry about further events.

"... anxiety, it's definitely a factor after my stroke. Just worrying about stupid things, things which might never happen..... if I try to do as much as I used to, then the next day I'm very tired. Is that part of the stroke?" (83yo, female)

Some reported difficulty with expressive language; others identified effects on memory or cognition.

"one thing I found after my stroke, is struggling over words. ....I thought it would be better by now." (60yo, female)

Participants suggested that the manual should include information about these problems. One patient commented that outcome measures could include an assessment of cognitive impairment; others suggested giving accelerometer feedback. It was also suggested that more open questions would encourage dialogue in follow-up and that patients should construct questions for subsequent contacts.

> *"…there were a few things that I would have liked to have been asked. …Perhaps say, before the next time …., write down a few questions which you would like to ask me." (60yo, male)*

Adding a food diary was suggested, perhaps utilising smartphone apps, to emphasize patients' ownership of their lifestyles.

> *" You don't know how bad your diet is until you write it down. I wouldn't have thought I would eat more than 3 bars of chocolate a month but when it is written down, it's more like 10 or 12." (57yo, female)*
>
> *"I have an app, …. it tells you the calories and so on. It's good for accountability." (60yo, male)*

Also, it was suggested that a 6-month follow-up might support maintained behaviour change.

> *"As time goes on and you get the confidence that you're not going to have another one, there is a danger that you can just drift back into bad habits ……..6 month review might motivate you further to get into a real life change habit." (60yo, male)*

Discussion

Summary

This study reports the use of an adapted home-based CR programme in patients within four weeks of their first TIA and/or 'minor' stroke of atherosclerotic origin. Over one third (44/125; 35%) of eligible patients consented to research contact; 90.9% (40/44) of these consented to participate and 97.5% (39/40) completed the study. All outcome assessments were positively received and fully completed.

These recruitment and retention rates provide evidence of the acceptability of the intervention and research protocol. Baseline assessments indicated participants' potential for improvement in stroke risk factors. Changes observed in intervention groups suggested that the programme may impact positively on stroke risk reduction. Focus group findings indicated that the intervention was acceptable to, and welcomed by, patients and that the programme addressed a perceived gap in their healthcare provision. Participants suggested that some additional information, particularly regarding post-TIA symptoms, and outcome measures, such as cognitive assessment, would contribute to the intervention's further development and appraisal.

Strengths and Limitations

Our intervention was developed within a theoretical and evidence-based framework. Physical activity was assessed objectively using an accelerometer and blood pressure was measured using BpTru, which is equivalent to 24 hour blood pressure monitoring (22), a current standard for diagnosing hypertension (45). Patients were recruited from various levels of socio-economic deprivation and educational attainment, and from different healthcare Trusts, including urban and rural settings.

A GP (NH) led the study including conducting the interview and focus group and it is possible that participants' responses were affected in terms of limiting adverse comments. Blinding of participants, GP and SNs was impossible due to the nature of the intervention. However, engaging independent statisticians in randomisation and analysis, and blinding of the review assessor avoided bias in group allocation and outcome measurements. Consideration should be given to adjusting the intervention and research methods appropriately for participants with a disability and to collecting resource use data, to assess cost-effectiveness.

Comparison with existing literature

Our results indicate that this intervention promotes physical activity, endurance and balance, as reflected in the self-reported physical activity questionnaire, step-count, TUGT and 2MWT data in intervention groups. These findings concur with a recent Cochrane Systematic Review (43) which found that cardiorespiratory and mixed exercise training was effective in reducing disability in stroke survivors and promotion of walking increased mobility. Our findings confirmed the importance of managing post-TIA/'minor' stroke symptoms, including fatigue, mental health, and focal neurological symptoms (44). This intervention could be delivered by GPs to help maximise secondary prevention following a TIA or 'minor' stroke, particularly with the emphasis now on greater community management of these common conditions (41)(42).

Implications for research and/or practice

This pilot study of an innovative secondary prevention intervention, utilising core components of CR, for those suffering a first TIA or minor stroke within the preceding month, has shown that a randomised controlled trial to test its effectiveness is feasible, with

minor changes to the intervention and outcome measures. '*The Healthy Brain Rehabilitation Manual*' is a patient-centred rehabilitation programme, suitable for use in primary care, with potential for important clinical benefit in a patient cohort with high risk of stroke.

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Ethical Approval

The study was approved by the Office for Research Ethics Committees, Northern Ireland (REC reference 15/NI/0001, 21/09/2015) and registered (ClinicalTrials.gov, NCT02712385).

Competing Interests

None.

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How this fits in

Cardiac rehabilitation (CR) after myocardial infarction reduces risk of re-infarction, cardiac mortality and all-cause mortality but the value of CR after a TIA or 'minor' stroke is untested despite these conditions sharing similar pathology with coronary heart disease. Such patients are at high risk of future cardiovascular events but early intervention

following a TIA or ‘minor’ stroke may prevent further stroke and disability. As awareness of the importance of lifestyle factors rises, the best approach to implementing secondary prevention remains unknown. I therefore developed a novel home-based intervention, ‘*The Healthy Brain Rehabilitation*’, for use in primary care, using core components of CR to promote secondary prevention for TIA and ‘minor’ stroke patients and this intervention’s effectiveness should now be evaluated within a randomised controlled trial.

Figure 1

Figure 1 - CONSORT Flow diagram for Pilot Study

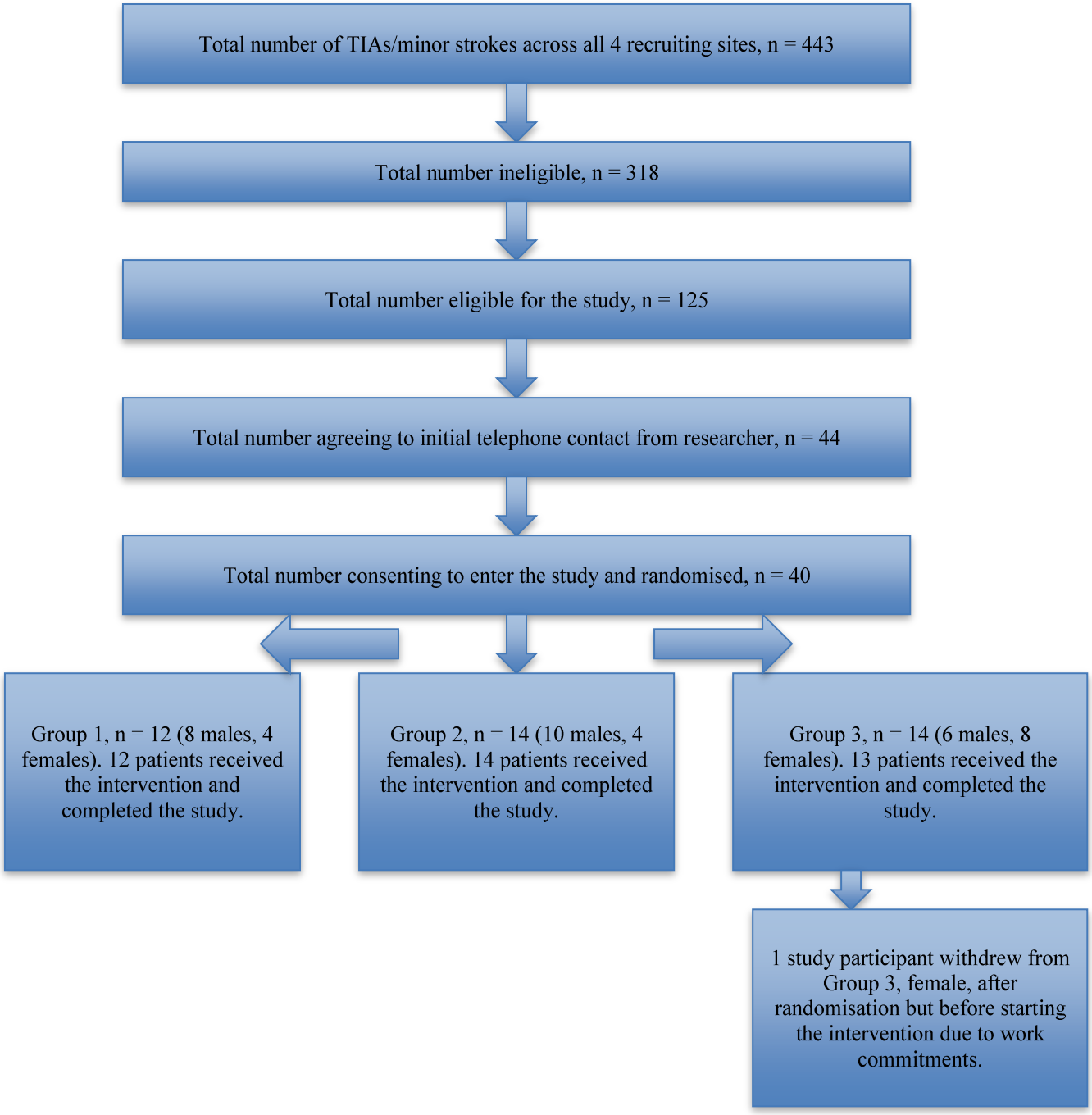

Table I – Comparison of Baseline and Post-Intervention Assessments

Variables	Group 1 (Control) (n=12) Baseline Mean (SD)	Group 1 (n=12) Post-intervention Mean (SD)	Group 2 (GP Follow-up) (n=14) Baseline Mean (SD)	Group 2 (n=14) Post-intervention Mean (SD)	Group 3 (Stroke Nurse follow-up) (n=14) Baseline Mean (SD)	Group 3 Post-intervention (n=13) Mean (SD)
Systolic BP (mmHg)	140.4 (23.67)	140.8 (8.03)	137.9 (16.36)	127.6 (9.95)	129.4 (19.75)	130.7 (15.79)
Diastolic BP (mmHg)	84.17 (12.27)	83.58 (16.59)	88.9 (11.74)	80.50 (8.22)	81.00 (14.53)	82.31 (7.50)
Waist circumference (cms)	99.83 (10.56)	102.8 (11.43)	104.3 (15.38)	102.8 (13.98)	93.92 (10.16)	93.63 (10.52)
^BMI	28.98 (3.89)	29.2 (4.35)	29.75 (6.68)	29.20 (6.28)	28.02 (2.95)^	27.72 (3.25)^
Mediterranean diet score	3.08 (1.56)	3.46 (1.70)	4.50 (1.79)	7.64 (2.06)	3.57 (2.59)	6.92 (2.78)
HADs total score	7.50 (3.06)	6.67 (5.30)	9.36(6.77)	5.64 (5.93)	13.21 (10.93)	8.77 (9.51)
EQ5D-5L index score	0.84 (0.12)	0.84 (0.21)	0.79 (0.17)	0.85 (0.24)	0.67 (0.30)	0.86 (0.15)
VAS score (EQ5D-5L)	65.83 (13.29)	66.25 (11.70)	62.86 (21.90)	71.79 (14.76)	69.64 (15.99)	76.92 (17.50)
^Two minute walk test(metres)	127.5 (33.09)	126.6 (45.84)	143.5 (53.76)	159.0 (50.27)	142.2 (38.59)^	160.4 (37.79)^
^TUGT, seconds	13.33 (6.50)	12.19 (7.63)	12.9 (7.04)	9.34 (5.80)	10.50 (5.96) ^	8.15 (2.79)^
IPAQ (MET/minutes/week)	1287 (1738)	2534 (4055)	1104 (1883)	4060 (4865)	1276 (1397)	6787 (13047)
IPAQ sitting(minutes/day)	452.5 (229.4)	390.0 (223.8)	533.6 (247.0)	312.9 (156.4)	520.0 (351.5)	378.5 (347.6)
Number sitting ≥5 hours	8	8	11	8	10	7
****Steps/day**			5,546 (4,127)**	6710 (4585)**	6,538 (3,993)**	8423 (4686)**
Accelerometer(minutes/day)*						
- Sedentary time	1266 (72.18)	1266 (90.02)	1240 (73.83)	1210 (110.6)	1230 (108.1)	1236 (98.50)
- MVPA	137.6 (66.21)	137.1 (79.14)	163.6 (68.75)	190.2 (103.9)	176.9 (100.8)	170.5 (93.29)

****Baseline: Group, 2 n=14, Group 3, n=13; Post-intervention: Group 2, n=10, Group 3, n=10. *Baseline: Group 3, n=13; Post-intervention: Group 1, n=12, Group 2 n=13, Group 3, n=12. ^Group 3: baseline n-13; post-intervention n=12**

Abbreviations: BP=blood pressure; SD=standard deviation; TUGT=Timed Up and Go test; MVPA=moderate and vigorous physical activity

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